IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB, Plaintiffs/Counterclaim-Defendants, v. AGILA SPECIALTIES, INC. et al., Defendants/Counterclaim- Plaintiffs.	Civil Action No. 1:15–cv–06039-RMB-KMW (consolidated)
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB, Plaintiffs/Counterclaim-Defendants, v. MYLAN PHARMACEUTICALS INC. et al., Defendants/Counterclaim-Plaintiffs.	Civil Action No. 1:15-cv-7009-RMB-KMW
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB, Plaintiffs/Counterclaim-Defendants, v. TEVA PHARMACEUTICALS USA, INC., Defendant/Counterclaim-Plaintiff.	Civil Action No. 1:15-cv-7889-RMB-KMW
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB, Plaintiffs/Counterclaim-Defendants, v. INNOPHARMA LICENSING LLC, Defendant/Counterclaim-Plaintiff.	Civil Action No. 1:16-cv-1962-RMB-KMW
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB, Plaintiffs/Counterclaim-Defendants, v. MYLAN INSTITUTIONAL LLC, Defendant/Counterclaim-Plaintiff.	Civil Action No. 1:16-cv-4612-RMB-KMW **JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT**

Pursuant to Local Patent Rule 4.3 and the Court's Scheduling Order dated May 11, 2016, Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and AstraZeneca AB (collectively, "Plaintiffs" or "AstraZeneca"), and Defendants Agila Specialties, Inc. (f/k/a Strides Inc.), Onco Therapeutics Limited, Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, Mylan Inc., and Mylan Institutional LLC (collectively, "Mylan"), Teva Pharmaceuticals USA, Inc. ("Teva"), and InnoPharma Licensing LLC ("InnoPharma") (collectively, "Defendants"), submit this Joint Claim Construction and Prehearing Statement for U.S. Patent Nos. 6,774,122 ("the '122 Patent"), 7,456,160 ("the '160 Patent"), 8,329,680 ("the '680 Patent"), and 8,466,139 ("the '139 Patent") (collectively, "the Patents-in-Suit") in the above-captioned matters, which have been consolidated for all purposes under lead case, Civil Action No. 1:15–cv–06039-RMB-KMW.

I. Background

In these Hatch-Waxman patent actions, Plaintiffs are asserting infringement of the Patents-in-Suit against Defendants based on, *inter alia*, Defendants' submission of Abbreviated New Drug Applications (ANDA) seeking to market generic fulvestrant injection, 250 mg/5 mL (50 mg/mL) pre-filled syringes prior to expiration of the Patents-in-Suit. Defendants have counterclaimed that the Patents-in-Suit are not infringed and are invalid. Mylan Institutional LLC has also counterclaimed that the Patents-in-Suit are unenforceable due to inequitable conduct; the remaining Defendants have moved to add such counterclaims that the Patents-in-Suit are unenforceable due to inequitable conduct.

A. The '122 Patent

The '122 Patent includes two independent claims and seven dependent claims. AstraZeneca currently asserts Claims 1-5 and 9 of the '122 Patent ("the '122 Asserted Claims") against Defendants. The '122 Asserted Claims recite[1] (disputed terms underlined):

1. A method of treating a hormonal dependent benign or malignant disease of the breast or reproductive tract by administration to a human in need of such treatment an intra-muscular injection of a pharmaceutical formulation comprising fulvestrant, a mixture of 10% weight of ethanol per volume of formulation, 10% weight of benzyl alcohol per volume of formulation and 15% weight of benzyl benzoate per volume of formulation and a sufficient amount of a castor oil vehicle, whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection.

2. The method as claimed in claim 1 wherein the benign or malignant disease is breast cancer.

3. The method as claimed in claim 1 wherein the blood plasma fulvestrant concentration is attained for at least 4 weeks after injection.

4. The method as claimed in claim 1 wherein the blood plasma fulvestrant concentration is attained for 2 to 5 weeks after injection.

5. A method of treating a hormonal dependent benign or malignant disease of the breast or reproductive tract by administration to a human in need of such treatment an intra-muscular injection of a pharmaceutical formulation comprising fulvestrant, a mixture of 10% weight of ethanol per volume of formulation, 10% weight of benzyl alcohol per volume of formulation and 15% weight of benzyl benzoate per volume of formulation and a sufficient amount of a castor oil vehicle whereby the formulation comprises at least 45 $mgml^{-1}$ of fulvestrant.

9. The method as claimed in claim 5 wherein the benign or malignant disease is breast cancer.

B. The '160 Patent

The '160 Patent includes two independent claims and ten dependent claims. AstraZeneca currently asserts Claim 4 of the '160 Patent ("the '160 Asserted Claim") against Defendants. The '160 Asserted Claim recites (disputed terms underlined):

[1] A certificate of correction was issued with respect to the '122 Patent on October 16, 2007. The '122 Asserted Claims described herein incorporate the corrections.

1. (Not asserted; included for reference only)

A method of treating a hormonal dependent benign or malignant disease of the breast or reproductive tract by administration to a human in need of such treatment an intra-muscular injection of a pharmaceutical formulation comprising fulvestrant, a mixture of from 10 to 30% weight of ethanol and benzyl alcohol per volume of formulation and 10 to 25% weight of benzyl benzoate per volume of formulation and a sufficient amount of a castor oil vehicle, whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection.

2. (Not asserted; included for reference only)

A method of treating a hormonal dependent benign or malignant disease of the breast or reproductive tract by administration to a human in need of such treatment an intra-muscular injection of a pharmaceutical formulation comprising fulvestrant, a mixture of from 10 to 30% weight of a mixture of ethanol and benzyl alcohol per volume of formulation and from 10 to 25% weight of benzyl benzoate per volume of formulation and a sufficient amount of a castor oil vehicle, whereby the formulation comprises at least 45 $mgml^{-1}$ of fulvestrant.

4. The method as claimed in claim 1 or 2 wherein the formulation comprises a mixture of from 8.5 to 11.5% weight of ethanol per volume of formulation and from 8.5 to 11.5% weight of benzyl alcohos [sic] per volume of formulation an [sic] 12 to 18% weight of benzyl benzoate per volume of formulation.

C. The '680 Patent

The '680 Patent includes two independent claims and eighteen dependent claims. AstraZeneca currently asserts Claims 1-7 and 17 of the '680 Patent ("the '680 Asserted Claims") against Defendants. The '680 Asserted Claims recite (disputed terms underlined):

1. A method for treating a hormonal dependent benign or malignant disease of the breast or reproductive tract comprising administering intramuscularly to a human in need of such treatment a formulation comprising:
about 50 $mgml^{-1}$ of fulvestrant;
about 10% w/v of ethanol;
about 10% w/v of benzyl alcohol;
about 15% w/v of benzyl benzoate; and
a sufficient amount of castor oil vehicle;
wherein the method achieves a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ for at least four weeks.

2. The method of claim 1, wherein the therapeutically significant blood plasma fulvestrant concentration is at least 8.5 $ngml^{-1}$.

3. The method of claim 1, wherein the hormonal dependent benign or malignant disease of the breast or reproductive tract is breast cancer.

4. The method of claim 1, wherein the method comprises administering intramuscularly to a human in need of such treatment 5 mL of the formulation.

5. The method of claim 1, wherein the method further comprises once monthly administration of the formulation.

6. The method of claim 2, wherein the hormonal dependent benign or malignant disease of the breast or reproductive tract is breast cancer.

7. The method of claim 6, wherein the method comprises administering intramuscularly to a human in need of such treatment 5 mL of the formulation.

17. The method according to claim 1, wherein the formulation is administered in a divided dose.

D. The '139 Patent

The '139 Patent includes two independent claims and eighteen dependent claims. AstraZeneca currently asserts Claims 2, 3, 10, 12, 13 and 20 of the '139 Patent ("the '139 Asserted Claims") against Defendants. The '139 Asserted Claims recite (disputed terms underlined):

1. (Not asserted; included for reference only)

A method for treating a hormonal dependent benign or malignant disease of the breast or reproductive tract comprising administering intramuscularly to a human in need of such treatment a formulation comprising:
about 50 $mgml^{-1}$ of fulvestrant;
a mixture of from 17-23% w/v of ethanol and benzyl alcohol;
12-18% w/v of benzyl benzoate; and
a sufficient amount of castor oil vehicle;
wherein the method achieves a blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ for at least two weeks.

2. The method of claim 1, wherein formulation comprises a mixture of from 19-21% w/v of ethanol and benzyl alcohol and 14-16% w/v of benzyl benzoate.

3. The method of claim 1, wherein formulation comprises:
about 10% w/v of ethanol;
about 10% w/v of benzyl alcohol; and
about 15% w/v of benzyl benzoate.

10. The method of claim 3, wherein the hormonal dependent benign or malignant disease of the breast or reproductive tract is breast cancer and the blood plasma fulvestrant concentration is attained for at least 4 weeks.

11. (Not asserted; included for reference only)

A method for treating a hormonal dependent benign or malignant disease of the breast or reproductive tract comprising administering intramuscularly to a human in need of such treatment a formulation consisting essentially of:
about 50 $mgml^{-1}$ of fulvestrant;
a mixture of from 17-23% w/v of ethanol and benzyl alcohol;
12-18% w/v of benzyl benzoate; and
a sufficient amount of castor oil vehicle;
wherein the method achieves a blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ for at least two weeks.

12. The method of claim 11, wherein formulation consists essentially of a mixture of from 19-21% w/v of ethanol and benzyl alcohol and 14-16% w/v of benzyl benzoate.

13. The method of claim 11, wherein formulation consists essentially of:
about 10% w/v of ethanol;
about 10% w/v of benzyl alcohol; and
about 15% w/v of benzyl benzoate.

20. The method of claim 13, wherein the hormonal dependent benign or malignant disease of the breast or reproductive tract is breast cancer and the blood plasma fulvestrant concentration is attained for at least 4 weeks.

II. Local Patent Rule 4.3

A. Construction of Claim Terms on Which the Parties Agree (L. Pat. R. 4.3(a))

In accordance with L. Pat. R. 4.3(a), the parties identify the following claim constructions on which they agree:

Claim Term	Patent and Claim No.	Agreed-upon Construction
"a sufficient amount of castor oil vehicle" / "a sufficient amount of a castor oil vehicle"	'122 patent claims 1–5; 9 '160 patent claim 4; '680 patent claims 1–7, 17; '139 patent claims 2–3, 10, 12–13, 20	"besides fulvestrant and any other excipients, the remaining volume is filled with castor oil"[2]

B. Each Party's Proposed Construction of Each Disputed Term and Identification of Intrinsic and Extrinsic Evidence (L. Pat. R. 4.3(b))

In accordance with L. Pat. R. 4.3(b), the parties provide the following chart summarizing the contested terms, proposed constructions, and applicable patent and claim numbers. These constructions are provided without prejudice to the right of Plaintiffs or Defendants to seek construction of additional claim terms or to modify or supplement these constructions based on any evidence, facts, documents, or information not yet considered or not yet determined to be relevant.

Term Identified for Construction	Patent and Affected Claims No(s).	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
"Fulvestrant"	'122 patent claims 1–5, 9 '160 patent claim 4; '680 patent claims 1–7, 17;	ordinary meaning	"7α-[9-(4,4,5,5,5-pentafluoropentylsulphinyl)nonyl]oestra-1,3,5(10)triene-3,17β-diol, including pharmaceutically

[2] The parties have agreed upon construction of this term on the basis that the differences in the parties' respective preferred constructions will not be used as a basis to challenge the validity or infringement of the Patents-in-Suit, including that the Defendants will not be asserting indefiniteness based on this term.

Term Identified for Construction	Patent and Affected Claims No(s).	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
	'139 patent claims 2–3, 10, 12–13, 20		acceptable salts thereof, and any possible solvates of either thereof"
"whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection"	'122 patent claims 1–4; '160 patent claim 4 (depending from unasserted independent claim 1)	"the blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is achieved and maintained for at least 2 weeks"	This term in non-limiting
"wherein the blood plasma fulvestrant concentration [of at least 2.5 $ngml^{-1}$] is attained for at least 4 weeks after injection"	'122 patent claim 3	"the blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is achieved and maintained for at least 4 weeks"	This term in non-limiting
"wherein the blood plasma fulvestrant concentration [of at least 2.5 $ngml^{-1}$] is attained for 2-5 weeks after injection"	'122 patent claim 4	"the blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is achieved and maintained for 2-5 weeks"	This term in non-limiting
"wherein the method achieves a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ for at least four weeks"	'680 patent claims 1–7, 17	"the blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is achieved and maintained for at least 4 weeks"	This term in non-limiting
"wherein the therapeutically significant blood plasma fulvestrant concentration is at least 8.5 $ngml^{-1}$ [for at least four weeks]"	'680 patent claims 2, 6, 7	"the blood plasma fulvestrant concentration of at least 8.5 $ngml^{-1}$ is achieved and maintained for at least 4 weeks"	This term in non-limiting
"wherein the method achieves a blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ for at least two weeks"	'139 patent claims 2–3, 12–13, (depending from unasserted independent claims 1,11)	"the blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is achieved and maintained for at least 2 weeks"	This term in non-limiting

Term Identified for Construction	Patent and Affected Claims No(s).	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
"wherein . . . the blood plasma fulvestrant concentration [of at least 2.5 $ngml^{-1}$] is attained for at least 4 weeks"	'139 patent claims 10, 20	"the blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is achieved and maintained for at least 4 weeks"	This term in non-limiting

In accordance with L. Pat. R. 4.3(b), the parties further provide attached Exhibits A-D, which contain a table comparing Plaintiffs' and Defendants' proposed constructions for each disputed term in the '122 Patent (Exhibit A), the '160 Patent (Exhibit B), the '680 Patent (Exhibit C), and the '139 Patent (Exhibit D), as well as all intrinsic evidence the party contends supports its proposed construction and any extrinsic evidence known to the party on which it intends to rely either to support its proposed construction or to oppose any other party's proposed construction.

C. Identification of Most Significant Terms (L. Pat. R. 4.3(c))

1. Plaintiffs' Statement

In accordance with L. Pat. R. 4.3(c), Plaintiffs state that none of the claim construction issues are potentially significant to resolution of the case, or case or claim dispositive or substantially conducive to promoting settlement. With respect to the term "fulvestrant," Defendants have indicated that their construction of fulvestrant is devised solely to create an argument of validity based on written description and enablement. AstraZeneca respectfully requests the Court construe "fulvestrant" in accordance with its plain and ordinary meaning to a person of skill in the art.

With respect to the blood plasma fulvestrant concentration limitations (e.g., wherein the therapeutically significant blood plasma fulvestrant concentration is at least 8.5 $ngml^{-1}$ for at least four weeks), Defendants do not challenge the Court's previous construction of these terms.

Rather, Defendants only argue that these claim terms should not be considered limitations at all for the purposes of supporting their validity arguments. Accordingly, the Court need not reconsider its previous construction of these claim limitations.

2. Defendants' Statement

In accordance with L. Pat. R. 4.3(c), Defendants state that the construction of the term "fulvestrant" is particularly significant as it is potentially dispositive of every claim asserted in this litigation. As such, the construction of that term may be substantially conducive to promoting settlement. Contrary to Plaintiffs' characterization—that Defendants' construction is "devised" to "create an argument" regarding invalidity—Defendants merely ask the Court to maintain its prior construction of that term; in contrast, Plaintiffs press a construction that has already been rejected by the Court in a prior case construing the Patents-in-Suit.

Defendants also state that the construction of the various "wherein" and "whereby" terms listed above and whether those terms are limiting is significant to the resolution of the case as it will streamline the issue of invalidity of the Patents-in-Suit.

D. Anticipated Length of Time Necessary for Claim Construction Hearing

In accordance with L. Pat. R. 4.3(d), the parties anticipate that the claim construction hearing will require no more than one day.

E. Anticipated Witnesses to be Called at Claim Construction Hearing

1. Plaintiffs' Statement

At this time AstraZeneca does not intend to call witnesses to provide live testimony at the *Markman* hearing but reserves its right to do so. AstraZeneca will provide the Court with a tutorial of the technology of the Patents-in-Suit if that would be useful to the Court.

AstraZeneca may rely on expert testimony to support its proposed constructions or to oppose Defendants' proposed constructions, to provide background information and scientific

explanation as to the state of the art and the knowledge of a person of ordinary skill at the time of the invention, or to address the meanings of claim terms as understood by a person of ordinary skill in the art.

2. Defendants' Statement

Defendants have no present intention to call witnesses to provide live testimony at the claim construction hearing with respect to the patents-in-suit, but reserve the right to do so. Defendants believe it would be beneficial for the Court to hear a technology tutorial with respect to the patents-in-suit.

Defendants may rely on expert testimony in support of Defendants' proposed claim constructions, and, if necessary, to rebut Plaintiffs' proposed claim constructions. If asked to testify via deposition or provide a declaration on Defendants' behalf, Defendants' expert may provide a brief tutorial regarding "fulvestrant," the purported invention of the patents-in-suit, method(s) of administering fulvestrant, methods of treating hormonal dependent benign or malignant disease of the breast or reproductive tract, and related subject matter.[3]

[3] All parties, in their disclosures pursuant to L. Pat. R. 4.3(e), have reserved the right to rely on expert testimony in support of their proposed claim constructions, or as part of a claim construction tutorial. No party has identified any particular expert or any details of any potential expert's testimony. The parties have respectfully agreed, subject to the Court's view or further direction, that disclosures of claim construction experts and their testimony will be made with the parties' opening claim construction submissions, and that no party will object to such disclosure as untimely or not otherwise in compliance with L. Pat. R. 4.2 or 4.3.

Respectfully submitted,

Dated: September 2, 2016

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EXHIBIT A

'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Defendants' Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
"fulvestrant"	Plain and ordinary meaning to a person of skill in the art—i.e., the international non-proprietary name for the chemical compound, 7α-[9-(4,4,5,5,5-pentafluoropentylsulphinyl)nonyl]oestra-1,3,5(10)-triene-3,17β-diol. **Intrinsic Evidence** ***Patent Specification*** • '122 Patent col.1, ll.64-67. • '122 Patent col.2, ll.47-54. • '122 Patent col.4, l.66-col.5, l.24 & tbl.2. • '122 Patent col.5, ll.42-57. • '122 Patent col.8, ll. 29-50. • '122 Patent col.9, ll.1-14. • '122 Patent col.9, l.20-col.10, l.55 & tbls.3 & 4, fig.1. **Extrinsic Evidence** ***References*** • Powell et al., *Compendium of Excipients for Parenteral Formulations*, 52 J. Pharm. Sci. Tech. 238 (1998) (AZF00268987). ***Expert Witness Testimony*** • If necessary, an expert(s) will testify on background on the pharmaceutical formulation process, including pharmaceutical compounds, salts and solvates, and that "fulvestrant" in the context of the intrinsic evidence, including the evidence referred to above, has its ordinary meaning.	Term has already been construed by the Court: "7a-[9-(4,4,5,5,5-pentafluoropentylsulphinyl)nonyl]oestra-1,3,5(10)-triene-3,17~-diol, including pharmaceutically acceptable salts thereof, and any possible solvates of either thereof" **Intrinsic Evidence** ***Patent Specification*** • '122 pat., col. 1, l. 51–col. 2, l. 2; col. 2, ll. 36–40 • '122 Patent, Abstract • '122 Patent col.1:1–15 • '122 Patent col.1:64–2:2 ***Prosecution History*** • '122 patent, 6/3/2003 Amendment and Response, AZF00000655–69 **Extrinsic Evidence** • U.S. Patent No. 4,659,516, AZF00716989–7010 • U.S. Patent No. 6,417,191, AZF2_00005454–66 • Guidance on INN, World Health Organization, http://www.who.int/medicines/services/inn/innquidance/en/ (last visited 8/2/2016), AZF2_00005614–5617 • *AstraZeneca et al. v. Sandoz et al.*, No. 14–3547 (D.N.J. July 29, 2015), D.I. 102, AZF2_00040621–25 ***Expert Witness Testimony*** • If necessary, an expert(s) will testify that

EXHIBIT A

'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Defendants' Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		"fulvestrant" in the context of the intrinsic and extrinsic evidence, including the evidence referred to above and in Plaintiffs' and Defendants' disclosures pursuant to L.P.R. 4.2(b), and consistent with the ordinary meaning, includes salts or solvates of fulvestrant.
"whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks"	Defendants do not propose a competing construction to that previously determined by the Court. Accordingly, there is no need for the Court to construe this term. "the blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is achieved and maintained for at least 2 weeks" **Intrinsic Evidence** ***Claim Language*** • The claims provide context and are self-limiting as the "method of treatment" requires administering "a pharmaceutical formulation" by "intra-muscular injection" to "a human in need of such treatment" • Claim language of the '122, '160, '680 and '139 Patents ***Specification*** • '122 Patent col.1, ll.4-5. • '122 Patent col.6, ll.1-6. • '122 Patent col.9, ll.1-4, 7-14. • '122 Patent col.11, ll.4-9.	These clauses are non-limiting as they merely express an intended result. **Intrinsic Evidence** ***Specification*** • '122 patent, col. 2, ll. 65–67; col. 5, ll. 25–35, 38–39, 62–67; col. 6, ll. 1–6, 13–16, 24–26, 55–64; col. 8, ll. 29–32, 61–67, col. 9, ll. 1–14; col. 10, ll. 24–67; Fig. 1 ***Prosecution History*** • '122 patent, 2/1/2002 IDS Enclosure at AZF00000175-87 • '160 patent, 8/21/2008 Amendment and Gellert Declaration, AZF00000884–929 • '680 patent, 12/21/2010 Office Action, AZF00002281–2289 ***Intrinsic Prior Art*** • Anthony Howell et al., *Pharmacokinetics, Pharmacological and Anti-tumour Effects of the Specific Anti-oestrogen ICI 182780 in Women with Advanced Breast Cancer*, 74 BRIT. J. CANCER 300, 302 (1996) (referenced on face of the '160 patent), AZF00276306–14

EXHIBIT A

'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Defendants' Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence

	Prosecution History
	• Office Action (Dec. 3, 2002).
	• Amendment and Response (June 3, 2003).
	• Declaration and Amendment and Response (Aug. 21, 2008).
	• Office Action (Dec. 21, 2010).
	• Response (June 20, 2011).
	• Declaration and Amendment and Response (Jan. 17, 2012).
	
	Intrinsic Prior Art
	• *Remington's Pharmaceutical Sciences* 1676-93 (Alfonso R. Gennaro, ed., 18th ed. 1990).
	
	Extrinsic Evidence
	• Ansel, *Pharmaceutical Dosage Forms and Drug Delivery Systems* 101-141 (AZF00269599).
	
	Court's Claim Construction
	• Order, *AstraZeneca Pharms. LP et al. v. Sandoz Inc. et al.*, 14-cv-03457-RMB-KMW, ECF No. 102.
	
	Expert Witness Testimony
	• If necessary, an expert(s) will testify on background on the pharmaceutical formulation process, including measurements of plasma levels, and that "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection" in the context of the
		Extrinsic Evidence
		• Testimony of John Robertson, *AstraZeneca Pharmaceuticals, LP et al. v. Sagent Pharmaceuticals, Inc. et al.*, Case No: 1:14-cv-3547-RMB-KMW (D.N.J.)
		• Testimony of Ronald Sawchuk, *AstraZeneca Pharmaceuticals, LP et al. v. Sagent Pharmaceuticals, Inc. et al.*, Case No: 1:14-cv-3547-RMB-KMW (D.N.J.)
		• Faslodex® label (e.g., AZF00180210–226)
		
		Expert Witness Testimony
		• If necessary, an expert(s) will testify that the preceding portions of the claim are complete and that a person of ordinary skill in the art would understand the claimed blood plasma fulvestrant concentrations to add nothing to the steps claimed.
		• If necessary, an expert(s) will testify as to the following:
		  ○ the preceding portions of the claim are complete and that a person of ordinary skill in the art would understand the claimed blood plasma fulvestrant concentrations to add nothing to the steps claimed
		  ○ the understanding of a "sustained release," 'extended release," and/or intramuscular "depot" formulation
		  ○ the practice, method, interpretation, and necessity (if any) of measuring blood

EXHIBIT A

'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Defendants' Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	intrinsic evidence, including the evidence referred to above and consistent with the ordinary meaning, means "the blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is achieved and maintained for at least 2 weeks." • If necessary, an expert(s) will testify that "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 ngml-1 is attained for at least 2 weeks after injection" is a limitation of the claims as demonstrated by the evidence, including the evidence referred to above and that a person of ordinary skill in the art at the time of the invention would have understood it to be a separate limitation of the invention.	plasma fulvestrant concentration levels as part of a method of treating hormonal dependent benign or malignant disease of the breast or reproductive tract by administration to human in need of such treatment an intramuscular injection of a pharmaceutical formulation
"wherein the blood plasma fulvestrant concentration is attained for at least 4 weeks"	Defendants do not propose a competing construction to that previously determined by the Court. Accordingly, there is no need for the Court to construe this term. "the blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is achieved and maintained for at least 4 weeks" *See evidence for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection" above.*	These clauses are non-limiting as they merely express an intended result. *See evidence above for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection"*
"wherein the blood plasma fulvestrant	Defendants do not propose a competing construction to that previously determined by the Court.	These clauses are non-limiting as they merely express an intended result.

EXHIBIT A

'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	**AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence**	**Defendants' Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence**
concentration is attained for 2 to 5 weeks"	Accordingly, there is no need for the Court to construe this term. "the blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is achieved and maintained for 2 to 5 weeks." *See evidence for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection" above.*	*See evidence above for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection"*

EXHIBIT B

'160 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Defendants' Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
"fulvestrant"	Plain and ordinary meaning to a person of skill in the art—i.e., the international non-proprietary name for the chemical compound, 7α-[9-(4,4,5,5,5-pentafluoropentylsulphinyl)nonyl]oestra-1,3,5(10)-triene-3,17β-diol. *See evidence for "fulvestrant" in the '122 Patent.*	Term has already been construed by the Court: "7a-[9-(4,4,5,5,5-pentafluoropentylsulphinyl)nonyl]oestra-1,3,5(10)-triene-3,17~-diol, including pharmaceutically acceptable salts thereof, and any possible solvates of either thereof" *See evidence for "fulvestrant" in the '122 Patent.*
"whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks"	Defendants do not propose a competing construction to that previously determined by the Court. Accordingly, there is no need for the Court to construe this term. "the blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is achieved and maintained for at least 2 weeks" *See evidence for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection" in the '122 Patent.*	These clauses are non-limiting as they merely express an intended result. *See evidence for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection" in the '122 Patent.*

EXHIBIT C

'680 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Defendants' Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
"fulvestrant"	Plain and ordinary meaning to a person of skill in the art—i.e., the international non-proprietary name for the chemical compound, 7α-[9-(4,4,5,5,5-pentafluoropentylsulphinyl)nonyl]oestra-1,3,5(10)-triene-3,17β-diol. *See evidence for "fulvestrant" in the '122 Patent.*	Term has already been construed by the Court: "7a-[9-(4,4,5,5,5-pentafluoropentylsulphinyl)nonyl]oestra-1,3,5(10)-triene-3,17~-diol, including pharmaceutically acceptable salts thereof, and any possible solvates of either thereof" *See evidence for "fulvestrant" in the '122 Patent.*
"wherein the method achieves a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ for at least four weeks"	Defendants do not propose a competing construction to that previously determined by the Court. Accordingly, there is no need for the Court to construe this term. "the blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is achieved and maintained for at least 4 weeks" *See evidence for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection" in the '122 Patent.*	These clauses are non-limiting as they merely express an intended result. *See evidence for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection" in the '122 Patent.*
"wherein the therapeutically significant blood plasma fulvestrant concentration is at least 8.5 $ngml^{-1}$"	Defendants do not propose a competing construction to that previously determined by the Court. Accordingly, there is no need for the Court to construe this term. "the blood plasma fulvestrant concentration of at least 8.5 $ngml^{-1}$ is achieved and maintained for at least 4 weeks"	These clauses are non-limiting as they merely express an intended result. *See evidence for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection" in the '122 Patent.*

EXHIBIT C

'680 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Defendants' Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	See evidence for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 ngml^{-1} is attained for at least 2 weeks after injection" in the '122 Patent.	

EXHIBIT D

'139 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Defendants' Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
"fulvestrant"	Plain and ordinary meaning to a person of skill in the art—i.e., the international non-proprietary name for the chemical compound, 7α-[9-(4,4,5,5,5-pentafluoropentylsulphinyl)nonyl]oestra-1,3,5(10)-triene-3,17β-diol. *See evidence for "fulvestrant" in the '122 Patent.*	Term has already been construed by the Court: "7a-[9-(4,4,5,5,5-pentafluoropentylsulphinyl)nonyl]oestra-1,3,5(10)-triene-3,17~-diol, including pharmaceutically acceptable salts thereof, and any possible solvates of either thereof" *See evidence for "fulvestrant" in the '122 Patent.*
"wherein the method achieves a blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ for at least two weeks"	"the blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is achieved and maintained for at least 2 weeks" *See evidence for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection" in the '122 Patent.*	These clauses are non-limiting as they merely express an intended result. *See evidence for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection" in the '122 Patent.*
"wherein . . . the blood plasma fulvestrant concentration is attained for at least 4 weeks"	"the blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is achieved and maintained for at least 4 weeks" *See evidence for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection" in the '122 Patent.*	These clauses are non-limiting as they merely express an intended result. *See evidence for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection" in the '122 Patent.*